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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/348,354 07/07/99 HAVENGA

M 4123US

EXAMINER

HM12/0417

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BEUNOVSKIS, P

ART UNIT

PAPER NUMBER

1632

DATE MAILED:

04/17/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary

Application No.
09/348,354

Applicant(s)
Havenga et al.

Examiner
Peter Brunovskis

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1632



– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jan 26, 2001
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 9-11, and 13-32 is/are pending in the application.
- 4a) Of the above, claim(s) 13-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 9-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirements.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some* c) ☐ None of:
- ☒ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- *See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) ☐ Other: _____

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DETAILED ACTION

The Examiner for the instant application has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed in accordance with the instructions at the end of this Action.

The response filed 1/26/01 has been entered as well as newly amended claims 1, 3-8, 11-14, and 20. Amendment of claims 1, 2, and 9 and entry of new claims 13-32 is acknowledged. Claims 1, 3-8, 9-11, and 13-32 are pending in the instant application. Applicant's arguments filed 1/26/00 will only be considered to the extent that they apply to the newly amended or pending claims; arguments directed to any other subject matter is considered moot.

Newly submitted claims 13-32 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Claims 13-32 are drawn to a method of selecting, producing, or generating a chimeric adenovirus or a library of chimeric adenoviruses comprising the use of nucleic acid library. Except for claims 9 and 10, all of the originally presented claims were drawn to vector or cell compositions; claim 12, cancelled after the first Office Action in the paper filed 7/01/00 recites a nucleic acid library comprising nucleic acid derived from different adenovirus serotypes.

Importantly, the nucleic acid library of originally presented claim 12 is drawn to a patentably distinct invention relative to the newly entered method claims. Moreover, Applicants noted in the Interview Summary of 6/16/00 (as described by Applicants in the response filed

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7/01/00; p. 6) that “claim 12 may be withdrawn from consideration and filed in a continuation”, consistent with Applicants cancellation of the claim in the amendment filed 7/01/00.

Notwithstanding Applicants cancellation of the claim, although the nucleic acid library invention and the method of using such in the newly entered claims are related as product and process of use, these inventions are distinct since the process for using the product as claimed can be practiced with another materially different product as recited in the method of claims 9-10 and since the nucleic acid library product as claimed can be used in a materially different process involving serotyping of adenoviral isolates by hybridization (see MPEP § 806.05(h)).

It is further noted that the method of claims 9-10 is distinct from the methods of newly entered claims 13-32, since each of these methods constitutes different and distinct method steps not sharing the same scope, set of reagents, methodology, or objective.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Because the newly claimed invention is directed to a non-elected invention by original presentation and because the newly claimed invention is distinct for the reasons given above and would require different, non-coextensive searches, claims 13-32 are withdrawn from consideration. See 37 CFR 1.142(b) and MPEP § 821.03.

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Information Disclosure Statement

Applicants statements concerning references cited by Crystal in a PTO-1449 form are noted. However, these statements cannot be properly evaluated, nor the references considered, since there is no evidence of record indicating that the Office has received any such PTO-1449 form as described. Clarification is requested.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 2 (and dependent claims) are indefinite in their recitation of the phrase “at least a part of fiber protein is adapted to provide [or exhibit, cl. 2]...a desired tropism to a plurality of target cells in a host” since it is unclear how “adapted” is defined or what its metes and bounds are in this context and because it is unclear whether the “adapt[ation]” is limited to the hand of man or whether it includes, e.g. a fiber “adaptation” naturally developed in the course of evolution.

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Claim 1 and 2 (and dependent claims) are indefinite in their recitation of “tropism” and “plurality” since it is unclear how these terms are defined or what their metes and bounds are *in the context of the claims*, what structural relationship or metes and bounds exist between the recited “tropism” and the “*plurality* of target cells”, particularly in the context of a host (emphasis added).

Claim 2 is indefinite in its recitation of “functional part” (of a fiber protein) since it is not clear what are the metes and bounds of this term in the context recited, given that any part of fiber protein is “functional” to the extent that it contributes one way or the other to the “functional characteristics” of the fiber protein.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 1-3 and 9-11 remain rejected under 35 U.S.C. 102(e) for the reasons set forth in the Office Action of 10/24/00 and for the reasons set forth below as being anticipated by Crystal et al. (US 6,127,525).

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Applicant's arguments filed 1/26/01 have been fully considered but they are not persuasive. The response contends that “[a] claim is anticipated only if each and every element set forth is found, either expressly *or inherently described* in a single prior art reference” (p. 9; emphasis added). The response further contends that “Crystal fails to expressly or inherently describe a chimeric adenoviral vector and methods of producing a chimeric adenoviral vector as presently claimed by applicants” (p. 10) and “does not describe ‘at least a part of a fiber protein adapted to provide the chimeric adenovirus with a desired tropism to a plurality of target cells in a host...[but is rather] narrowly drawn to chimeric adenovirus coat proteins configured for reduced antigenicity’ (paragraph abridging p. 10-11). Applicant further “submit[s] that Crystal teaches away from the subject limitation in that Crystal narrowly focuses on immunogenicity to the exclusion of a desired tissue tropism...[and that]...Crystal does not teach the claim 1 combination of elements drawn to: (1) a fiber protein of adapted to provide the chimeric adenovirus with a desired tropism to a plurality of target cells in a host, and (2) a penton or hexon protein from an adenovirus serotype differing from the serotype of the fiber protein, wherein the second adenovirus serotype has a lower relative tropism to the plurality of target cells than that of the chimeric virus” (p. 11).

In response to applicant's arguments directed to claim limitations, i.e. adapted to provide the chimeric adenovirus with a desired tropism, it is instructive to point out that insofar as the claim fails to recite any *structural difference* between the claimed invention and the prior art, so as patentably distinguish the claimed invention from the prior art, the prior art structure is

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interpreted to meet the limitations of the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

The compositions and methods comprising such as disclosed in claims 1-3 and 9-11 are directed to adenoviral vector embodiments only requiring: (1) “a part of a fiber protein” from one adenovirus serotype and (2) a penton or hexon from a second adenoviral serotype wherein the second serotype is less antigenic than the first serotype, and wherein the second serotype exhibits a “lower relative tropism” as compared to the resulting chimeric vector whose tropism is specified by the “part of the fiber protein” from the first adenovirus serotype. Even if the prior art disclosure did not recite or recognize a property or advantage that would flow naturally from following the suggestion of the prior art, this observation cannot serve as the basis for patentability over the prior art when the structural differences are otherwise identical. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

Applicants are correct to note that “[a] claim is anticipated only if each and every element set forth in the claim is found, either expressly *or inherently described*” (p. 9; emphasis added).

With regard to anticipation as it is directed in the instant case to inherency, the following quotation from MPEP 2112 applies:

“[w]here applicant claims a composition in terms of a function, property or characteristic and the composition of the prior art is the same as that of the claim but the function is not explicitly disclosed by the reference, the examiner may make a rejection under both 35 U.S.C. 102 and 103, expressed as a 102/103 rejection”.

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MPEP 2112 further states:

“[o]nce a reference teaching product appearing to be substantially identical is made the basis of a rejection and the examiner presents evidence or reasoning tending to show inherency, the burden shift to the applicant to show an obvious difference”.

Moreover, MPEP 2112.01 instructs that:

“Products of identical chemical composition can not have mutually exclusive properties.’ A chemical composition and its properties are inseparable”. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. *In re Spada*, 911 F.2d 705, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990).

As set forth in the Office Action of 10/24/00, Crystal teaches modification of adenoviral coat proteins (e.g. hexon or fiber) by replacement of the corresponding region from one adenoviral serotype with the corresponding coat protein region from another (i.e. second) adenoviral serotype. It should be noted, that whether Crystal et al. realized it or not, any adenoviral fiber protein within the context of their claimed invention has a particular tropism adapted for a particular plurality of target cells in a host, in accordance with Applicants teachings on p. 4, line 16 through p. 5, line 2. Further, when viewed in light of Applicants 37 C.F.R. 1.132 declaration, filed 8/01/00, it can be concluded, based on the evidence of record, gathered from above, that Crystal’s disclosure of the chimeric adenoviral vector of Example 5 (col. 27-28) anticipates the claimed subject matter. Specifically, Crystal discloses an adenoviral vector comprising a fiber protein from one adenovirus serotype, Ad5, and at least a part of a hexon protein from a second serotype, Ad7, wherein the second adenovirus serotype (i.e. Ad7) has lower relative tropism to a plurality of cells than the chimeric adenovirus (as specified by the Ad5

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fiber protein) and wherein the second adenovirus serotype (Ad7) has less antigenicity than the first adenovirus serotype (i.e. Ad5) as evidenced by Applicants 1.132 declaration (see e.g. Figure 1) and Table 2, p. 73 of the instant specification. In view of Applicants experimental data in the 1.132 declaration (compare and contrast Fig. 1-4) and the discrepancies between antigenicities of different Adenoviral serotypes, depending on the experimental conditions or origin(s) of human sera used (see e.g. Fig. 3, serotypes 27 vs. 28 and Fig. 4, serotypes 26 vs. 34), making the chimeric adenoviral vectors in accordance with Crystal's teachings as set forth in col. 7-8 would inherently anticipate the claimed subject matter. Since the instant claims are not patentably distinguishable from the disclosed subject matter of Crystal et al., Applicants have failed to overcome the prima facie case for anticipation.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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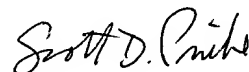
CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Certain papers related to this application may be submitted to Art Unit 1632 by facsimile transmission. The FAX number is (703) 308-4242 or 305-3014. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant *does* submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter Brunovskis whose telephone number is (703) 305-2471. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Karen Hauda can be reached at (703) 305-6608.

Any inquiry of a general nature or relating to the status of this application should be directed to the Patent Analyst, Patsy Zimmerman whose telephone number is (703) 308-8338.

Peter Brunovskis, Ph.D.
Patent Examiner
Art Unit 1632


SCOTT D. PRIEBE, PH.D.
PRIMARY EXAMINER